



June 20, 2005

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Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
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Docket No. 2004N-0463 Food Labeling; Prominence of calories;
Docket No. 2004N-0456 Food Labeling: Serving sizes of products
that can reasonably be consumed at one eating occasion; updating
of reference amounts customarily consumed; approaches for
recommending smaller portion sizes (70 FR 17008 & 17010;
April 4, 2005)

Dear Sir or Madam:

The Food Products Association (FPA) submits comments on the dockets
referenced above.

FPA is the largest trade association serving the food and beverage industry
in the United States and worldwide. FPA's laboratory centers, scientists
and professional staff provide technical and regulatory assistance to
member companies and represent the food industry on scientific and
public policy issues involving food safety, food security, nutrition,
consumer affairs, and international trade.

FPA believes that the questions proposed by the Food and Drug
Administration (FDA) in these Advanced Notices of Proposed
Rulemaking (ANPRM) are extremely important in consideration of
mechanisms by which consumers have and use information to make
informed decisions about food and beverages as part of healthy diets and
lifestyles in general, or for weight management or obesity prevention.
With the recent *2005 Dietary Guidelines for Americans* and the new U.S.
Department of Agriculture's (USDA) MyPyramid food guidance system,
the food label and its Nutrition Facts panel are a most essential part of a
trilogy of dietary guidance, food guidance, and food label information.

Alone, the food label and Nutrition Facts panel cannot effectively motivate Americans toward behavior change to improve health, food and dietary patterns, and increase physical activity. Contemporary American families purchase and consume foods and beverages from fresh and packaged sources; farmers markets, community and home gardens; and a variety of restaurants and retail or institutional food establishments. Addressing calories and serving size in labeling issues apart from other pending changes to labeling may confuse and not be in the best interest of American consumers, and increase economic burden on the food industry. A uniform approach for nutrition labeling changes, whether voluntary or required, must be coordinated to best serve consumers. For food labeling information to be used effectively, it will require education beyond information on the food label to guide decisions about food choices and consumption. Government must speak with one voice to educate consumers and American families about food, diet, nutrition, and health in promotion of healthful lifestyles.

Summary of Comments

FPA recommends that FDA proceed with only voluntary changes to food and nutrition labeling about calories and serving size. Main points addressed in our comments include:

- FDA must conduct systematic research and evaluation to demonstrate that consumer use, comprehension of, and performance with food label information motivate behavior change before issuing any proposals for new food labeling requirements related to calories and serving size.
- Government must recommit to public education about dietary guidance, food guidance, and use of label information and this must accompany any voluntary or required changes to food labeling.
- Current, contemporary American food consumption data are not yet available to evaluate and respond to questions about calories, serving size, or how to revise Reference Amounts Customarily Consumed (RACC) per eating occasion.
- Excessive focus on calories in labeling may undermine the “get the most nutrition from your calories” message of dietary and food guidance, and lead consumers to ignore foods or beverages with important nutrients, an unintended consequence that must be avoided.
- Calorie needs vary greatly and the individualized approach of MyPyramid may better serve the consumer.
- Current FDA regulations provide sufficient options to allow for voluntary dual labeling of calories or nutrition information in containers outside of single-serving container rules.
- FDA should consider new or alternative approaches beyond core questions about revision to RACCs.
- FDA must collect additional data to determine whether consumers can evaluate comparative claims about servings or portions.
- The prospect of numerous, incremental changes to the nutrition label is not in the consumer’s best interest and is unacceptable to the food industry. Any required labeling regulations need to be conducted simultaneously with one uniform implementation date.
- As additional consumer research and food consumption data are made available, FPA will submit additional comments to these ANPRMs.

Critical Need for Consumer Research and Public Education

FPA notes that there is incomplete information on which to adequately evaluate and respond to FDA's ANPRM questions. The consumer research base is either dated or incomplete related to assisting in understanding the questions posed in these ANPRMs. Thus, FPA urges FDA to conduct consumer research and testing that will systematically evaluate any potential labeling options for calories and serving size before issuing any voluntary guidance or proposed rules. It is imperative that any changes to food or nutrition labeling of calories or serving size motivate consumers toward behavior change in order to be effective in assisting with weight management or obesity prevention. Additionally, consumer research is required to demonstrate that a labeling change will achieve the intended outcomes in consumer understanding and behavior change before FDA proceeds with any mandated food or nutrition labeling requirements. In the interim, FPA urges that approaches to address calories and serving size information in labeling be advanced through voluntary measures.

In 21st Century America, the primary issue is about motivating consumers toward healthful lifestyles and not just focusing on calories alone or individual foods or beverages. Government investment and commitment to public education about food, diet, physical activity, health, and lifestyle is of greater importance since release of the *2005 Dietary Guidelines for Americans* and the MyPyramid food guidance system. Two central consumer messages of the 2005 Dietary Guidelines are, "Get the most nutrition out of your calories," and, "Find your balance between food and physical activity."¹ The new MyPyramid recommendations and its information tools similarly emphasize both calories and nutrient contributions from foods and beverages, and the need for increased physical activity.²

Both the 2005 Dietary Guidelines and MyPyramid recommend increased consumption of foods and beverages within food categories as part of an overall healthful diet. It is clear that most Americans should increase consumption of fruits, vegetables, beans, whole grains, low-fat dairy products, fish, and lean meat and poultry products. The food label alone cannot accomplish these recommended changes in dietary patterns. The "E," the education component, of the Nutrition Labeling and Education Act (NLEA), was never fully realized and has not been sufficient. Only a coordinated education campaign about dietary guidance, food guidance, and the food label can begin to achieve national goals for improved nutrient intake and overall diet and health.

FPA reminds FDA of our long-standing commitment to consumer education about food labeling. In 1993, as the National Food Processors Association (NFPA), we created *Label Facts for Healthful Eating*, an educator's resource guide to promote both understanding and use of the

¹ *Finding Your Way to a Healthier You: Based on the Dietary Guidelines for Americans*. 2005. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Accessed at <http://www.health.gov/dietaryguidelines/dga2005/document/pdf/brochure.pdf>. See also Executive Summary and Chapter 2 of Dietary Guidelines for Americans 2005. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Accessed at <http://www.health.gov/dietaryguidelines/dga2005/document/pdf/dga2005.pdf>.

² MyPyramid. 2005. U.S. Department of Agriculture. Accessed at <http://www.mypyramid.gov>.

Nutrition Facts panel on foods and beverages.³ *Label Facts* was developed by NFPA in cooperation with FDA and USDA's Food Safety and Inspection Service, along with a steering and review panel representing food industry, agriculture, education, health professions, and consumer groups. In 2004, we launched a new consumer education material based on Label Facts, entitled, *The Food Label & You: Following Food Labels for Healthy Weight Management*.⁴ *The Food Label & You* was developed to respond to FDA's *Calories Count* report and national attention to obesity prevention and weight management. This consumer education material is in the process of being updated to reflect the 2005 Dietary Guidelines and MyPyramid, and should be reissued by fall 2005. FPA will continue to assist in consumer education about the food label and hopes to work in collaboration and cooperation with both FDA and USDA.

FDA Consumer featured an article in 2002 titled, "Losing Weight: More Than Counting Calories."⁵ This article is one example that clearly outlines the need for a comprehensive approach to both food and activity behavior change for successful weight loss, weight management, or maintenance. Most importantly, FDA's *Calories Count* report underscored the need for change in areas beyond labeling of foods and beverages. FDA stated, "...obesity will be brought under control only as a result of numerous coordinated, complementary efforts from a variety of sectors of society," and, "weight control is primarily a function of balance of the calories eaten and calories expended on physical and metabolic activity."⁶ FDA's *Calories Count* report discussed the Agency's role in education, labeling, restaurants, therapeutics, and research, and outlined the need for comparable work on increasing physical activity across government and by public and private stakeholders.

Thus, FPA urges government to recommit to education about diet, physical activity, and healthful lifestyles to assist American families to achieve improved health. Without broad education, the effectiveness of the 2005 Dietary Guidelines, MyPyramid, and the Nutrition Facts panel (and entire food label) as a trilogy of education and information tools may not succeed to motivate consumers toward behavior change. Isolated efforts to change or add information in nutrition or food labeling without comprehensive food, diet, health, and lifestyle education programs likely will not achieve desired results for obesity prevention, weight management, or improved health outcomes. The opportunity to move forward in a coordinated manner must not be lost.

³ National Food Processors Association (now Food Products Association) in cooperation with the Food and Drug Administration, U.S. Department of Health and Human Services, and the Food Safety and Inspection Service, U.S. Department of Agriculture. 2003. *Label Facts for Healthful Eating: Educator's Resource Guide*. Washington, DC:NFPA. (out of print)

⁴ Food Products Association. *The Food Label & You: Following Food Labels for Healthy Weight Management*. Accessed at http://www.fpa-food.org/upload/pdfs/flv_printable.pdf.

⁵ *FDA Consumer*. Jan-Feb, 2002; revised April 2002. Accessed at <http://www.cfsan.fda.gov/~dms/fdweigh3.html>.

⁶ *Calories Count*. 2004. *Executive Summary*. Food and Drug Administration. Accessed at <http://www.cfsan.fda.gov/~dms/owg-toc.html>.

Calories

In general, FPA believes that, at present, data are insufficient to fully evaluate FDA's questions about calorie prominence, calorie and calorie from fat declarations, and other presentations about calories in food or nutrition labeling. The central question is, "Will changing the Nutrition Facts panel and other food labeling elements change consumer behavior with regard to calories?" As stated above, FDA must conduct comprehensive consumer research to evaluate any food and nutrition labeling changes regarding calories. Any proposed changes that would result in required label elements must be proven to be effective and achieve outcomes in consumer behavior.

In the interim, FPA believes that all options regarding calorie presentation (size, type, bolding, and principal display panel presentations [including %DV]) embodied in the ANPRM questions should be voluntary, and the presentation be clarified with appropriate FDA guidance to industry, if necessary. In addition, in the interest of transparency and to elucidate solutions, FPA urges FDA to complete and release reports of consumer research that were initiated during the work of the FDA Working Group on Obesity that led to the Agency's 2004 *Calories Count* report.

Because food labels only provide information to consumers, FPA has a concern that potential changes to expression of calorie information in nutrition labeling could lead to unintended consequences of consumers focusing too much on calorie information and not considering nutrition information about macronutrients, vitamins, minerals, electrolytes, and other components in foods and beverages. The balance between calories and nutrients—"Get the most nutrition out of your calories."⁷—is a central theme of the 2005 Dietary Guidelines. If consumers focus exclusively on calories, it may undermine nutrient contributions from the diet. Consumer research has shown that fat information in nutrition labeling receives priority attention from the public when reading food labels and using the Nutrition Facts panel.

Calories from Fat

The Institute of Medicine's Dietary Reference Intake report on Macronutrients and the 2005 Dietary Guidelines underscore the fact that calories from any source is more important information than a focus on calories from fat. The 2005 Dietary Guidelines state, "When it comes to body weight control, it is calories that count—not the proportions of fat, carbohydrate, and protein in the diet."⁸ A question related to this issue was posed to the Nutrition Subcommittee of the FDA Food Advisory Committee. The Nutrition Subcommittee recommended that total fat did not need to be a disqualifying nutrient for health claims related to

⁷ *Finding Your Way to a Healthier You: Based on the Dietary Guidelines for Americans*. 2005. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Accessed at <http://www.health.gov/dietaryguidelines/dga2005/document/pdf/brochure.pdf>. See also Dietary Guidelines for Americans 2005. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Executive Summary and Chapter 2. Accessed at <http://www.health.gov/dietaryguidelines/dga2005/document/pdf/dga2005.pdf>.

⁸ Dietary Guidelines for Americans 2005. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Chapter 3, Weight Management, p. 15. Accessed at <http://www.health.gov/dietaryguidelines/dga2005/document/pdf/dga2005.pdf>.

reduced risk of heart disease. Because the Nutrition Facts panel architecture was developed to focus on heart disease risk reduction, consumer research demonstrates that consumers place inappropriate focus on fat declarations and calories from fat rather than overall nutrition or calories per serving. For the above reasons, FPA believes that calories from fat declaration should not be required in nutrition labeling.

Percent Daily Value for Calories

As with other questions regarding additional calorie information in labeling, at present, FPA believes that there is insufficient evidence to evaluate current consumer use and understanding of current percent Daily Values (%DV) or new requirements for a %DV for calories. Over the years, consumer research has not demonstrated strong consumer understanding and use of %DV in nutrition labeling. Existing nutrition labeling regulations are clear that individual needs differ, as evidenced by presentation of 2,000 and 2,500 calorie information in the current Daily Value footnote, and the footnote language, "Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs."⁹

The 2005 Dietary Guidelines and MyPyramid acknowledge and underscore the importance of a wide variety of calorie levels depending upon age, gender, weight management goals, and physical activity level. MyPyramid's web-based tools have been created to fulfill the need for a personal and individualized approach to food guidance and recommendations for food consumption by food groups. FPA believes that FDA should work with USDA to maximize the potential information and educational synergy between MyPyramid and the Nutrition Facts panel and food label.

Until comprehensive information is available to assess consumer use and understanding of the %DV in nutrition labeling, FPA opposes a requirement for expressing a %DV for calories. Because of the variability of individual caloric needs, FPA is concerned with the potential for unintended consequences of directing consumers to focus exclusively on calories without consideration of other nutrient content information in the Nutrition Facts panel. As stated earlier, FPA believes FDA must conduct comprehensive research and evaluation to understand consumers' use and utilization of %DV information about calories or Nutrition Facts panel nutrients and food components. Additionally, it is possible that current expression of 2,000 and 2,500 calories may be inappropriate for Americans in 2005 and beyond. Thus, FPA requests that FDA consider voluntary approaches to use of alternate information on calorie levels in nutrition labeling and to provide context about %DV.

Calorie Presentation on the Principal Display Panel

The ANPRM asks several questions about presentation of calorie information on the Principal Display Panel (PDP). FPA opposes any mandatory requirements for calorie presentation or "calorie flags" on the PDP because of the potential for the unintended consequence of excessive focus on calories absent other nutrient contributions of foods and beverages. Further, it would be inappropriate to single out energy in the absence of the nutrient contributions of foods and

⁹ 21 CFR 101.9(d)(9).

beverages and distract consumers. This is supported by the 2005 Dietary Guidelines and MyPyramid recommendations and focus for consumers to “get the most nutrition from their calories.”

FPA believes there is no merit to a mandatory label statement about calories outside of the Nutrition Facts panel. FPA reminds FDA that a uniform referral statement on all food labels with claims was required from 1993 to 1998, but removed under the FDA Modernization Act (FDAMA) because the Nutrition Facts panel was a very clear label element providing information about calories, serving size, and nutrient content.¹⁰ Focusing on a “nutrient du jour” through mandatory labeling requirements will not improve consumer understanding about diet and health. Further, FPA believes that market forces will encourage healthy competition in this area, negating the need for required PDP presentation of calorie information. FPA supports the ability under current food labeling regulations for manufacturers to include calorie and other nutrient information on the PDP.

In summary regarding questions about calorie presentation in food and nutrition labeling, FPA urges FDA to conduct thorough consumer research to evaluate calorie labeling issues. Past nutrition labeling research generally shows that consumers focus first on fat information before calorie information. We believe that only education can assist in motivating consumers to consider overall calories when choosing foods for a healthful diet, and it must not undermine attention to the nutritive contributions from foods. Thus, comprehensive consumer research and testing must demonstrate consumer understanding and behavior change before the Agency proceeds with any required changes to food or nutrition labeling regulations regarding calories.

Serving Sizes

FDA questions about serving sizes, single-serving containers, revision to Reference Amounts Customarily Consumed (RACC) per eating occasion, and comparative claims for labeling focus on three primary areas:

- How can serving size information assist consumers in deciding how much food or beverage they should consume?
- How do consumers recognize the differences between serving sizes on food labels and servings recommended in dietary guidance? What changes would assist consumers?
- What alternative ways could assist consumers to evaluate calorie and serving information and food consumption?

Americans consume foods and beverages purchased fresh and in packaged form; prepare foods and meals from multiple ingredients in their homes; obtain foods from home or community gardens, or public or farmers markets; and from retail and institutional food service outlets or restaurants. Because of the variety of food and beverage sources, both with and without label

¹⁰ 63 FR 26978. Food Labeling; Nutrient Content Claims—General Provisions. May 15, 1998. Removed requirement for, “See [appropriate panel] for information about [nutrient requiring disclosure] and other nutrients.” and replaced with, “See nutrition information for ____ content.” only when the use of the claim requires nutrient disclosure.

information, FPA believes that food label information alone about serving sizes, single serving containers, or containers that might be reasonably consumed at one eating occasion will be insufficient to fully educate Americans and their families about quantities of food to consume to balance calories for healthy weight and lifestyles, or to reduce weight and prevent obesity. As stated earlier, American consumers and their families require expanded government commitment to public education about food, diets, physical activity, healthful lifestyles and improved health outcomes.

Updating RACCs

FPA believes that information is either dated or incomplete to make informed responses to FDA's questions about updating Reference Amounts Customarily Consumed per eating occasion (RACC). The most current, contemporary food consumption data are required to assess amounts customarily consumed per eating occasion under current regulations. Clearly, food consumption patterns of Americans and food and beverage options and variety in the marketplace have evolved over the time from first determination of RACCs for serving sizes in the FDA 1993 nutrition labeling final rules. The public and the food industry will need to review summary tables of the 2001-2002 National Health and Nutrition Examination Survey (NHANES) data in order to determine what and how much Americans are consuming across how many eating occasions per day to evaluate questions related to RACCs and offer informed responses to FDA's questions.

With the release of USDA's MyPyramid food guidance system to support the 2005 Dietary Guidelines, past confusion between Food Guide Pyramid servings and Nutrition Facts panel servings should be reduced. The 2005 Dietary Guidelines and MyPyramid food intake patterns now recommend amounts of foods or beverages within food categories to meet nutrient needs. These now are expressed as total recommended amounts per day in household measures (cup or ounce equivalents, not servings) across a range of calorie needs based on individual needs. The Nutrition Facts panel now will be the source for serving size information for consumers to make comparisons among foods, and to provide information to assist in determining appropriate amounts to consume when building diets for healthy lifestyles or for weight management.

In the 1993 final rules for serving size, in evaluation of comments submitted regarding whether serving size should reflect amounts customarily consumed per eating occasion or recommended servings from dietary and food guidance, the Agency stated, "FDA believes that promoting recommended servings can best be addressed through public education."¹¹ FPA suggests that FDA explore ways to link food and nutrition label information with the context of MyPyramid food intake recommendations and the 2005 Dietary Guidelines. FPA believes that new approaches are needed, apart from labeling requirements, to inform and educate Americans about using food labels to build healthful diets and promote overall health. FPA supported expanded and flexible application of food guidance information in food labeling in comments to USDA as part of its Food Guide Pyramid reassessment activity.

¹¹ 58 FR 2232. Food Labeling; Serving Sizes. January 6, 1993.

FDA's questions focus primarily on potential increases to RACCs. FPA agrees with the Agency's concern that potential changes to RACCs might lead to encouraging overconsumption of calories or nutrients. However, the converse is an equally important consideration. As an example, food consumption data could show that the mean, median, or modal American is consuming less fruit or vegetable per eating occasion. A downward adjustment to RACCs for fresh, juice, frozen, canned or dried fruits and vegetables would be in direct conflict with the 2005 Dietary Guidelines and MyPyramid. Neither of these scenarios would be advantageous to Americans or public health, and neither can be adequately assessed with currently available data. The Nutrition Facts panel must not communicate information that would lead to unsound or unhealthy dietary practices. This would be in violation of the Federal Food, Drug, and Cosmetic Act that prohibits labeling that is false or misleading in any manner.

In addition to a review of the most up-to-date food consumption data per eating occasion to determine whether RACCs require changing, FPA suggests that FDA consider additional dimensions. Because many RACC categories cover a wide range of foods in the marketplace today, FPA believes it may be useful, on a case-by-case basis, for FDA to consider whether RACC categories may need to be redefined or reaggregated based on food consumption data and the marketplace. The existing petition process also would accommodate requests for change from industry or citizen petition.

Another suggestion would be to consider application of a "reasonable consumer" standard as part of any approach for revising or updating RACCs along with contemporary food consumption data. FDA reiterated its support of the "reasonable consumer" standard in its guidance for industry about qualified health claims for conventional foods and dietary supplements.¹² FDA stated that it believes "consumers are active partners in their own health care who behave in health promoting ways when they are given accurate health information."¹³ This and other new thinking may result in approaches that fulfill statutory requirements while providing the ability to strengthen the Nutrition Facts panel as an information tool to support dietary and food guidance, and require no wholesale revision to RACCs.

In summary, all stakeholders must be able to review contemporary food consumption data per eating occasion before commenting on approaches or criteria to revise RACCs. For the reasons stated above, FPA believes that FDA should not proceed further in this area without considering additional dimensions and until data are available for stakeholder review.

Single-serving Containers

FDA's questions about single-serving containers and expression of per serving and per package calorie or nutrition information also require thorough exploration of the most current food consumption data in order to respond to the ANPRM questions. Data on consumer understanding and use of alternate presentations of calorie or nutrition information per serving and per container is sparse, at best. Absent adequate data to evaluate FDA's questions, FPA

¹² 76 FR 78002. Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability. December 20, 2002.

¹³ 76 FR 78002 at 78004.

believes that options that fall outside of existing regulations for labeling of containers should be voluntary. Food manufacturers already have flexibility in existing regulations to present dual calorie or nutrition declaration in nutrition labeling. Thus, FPA believes that no further regulatory requirements are necessary. However, additional FDA guidance to industry may be useful for voluntary expression of dual labeling of calories per serving or package/container, or dual nutrition labeling per serving or package/container.

Comparative Claims Related to Calories, Servings, and Portions

As with other questions in FDA's ANPRMs, these questions are virtually impossible to answer absent current or additional data about food consumption and consumer understanding of food labeling and claims. However, FPA supports existing food labeling regulations that any food or beverage comparisons about calories, serving size, or portion must be truthful and not misleading. FDA may wish to consider using enforcement discretion to allow comparative claims about servings or portions that deviate from the existing nutrient content claims framework for nutrients (e.g., less, reduced, more), provided that such claims are truthful and not misleading.

Coordination of Nutrition Labeling Changes

As stated in previous comments to the Agency, FPA believes that FDA should not proceed rapidly, or piecemeal, with further required changes to the nutrition label. FPA believes that it is important to avoid the prospect of several sequential nutrition label revisions within the span of a few years. The importance of careful consideration and coordination are made even more apparent when the changes that FDA contemplates would affect nutrition labeling with respect to just a few lines or components of the Nutrition Facts panel. Companies with FDA-regulated food labels could be faced with several mandatory nutrition label changes over several years. Food labels will require quantitative declaration of *trans* fat content and food allergen ingredient labeling by January 2006. Beyond 2006, several nutrition labeling issues are pending or are priority actions for the Agency. These include labeling issues related to dietary contextual information about *trans* fat, saturated fat and cholesterol; calories and serving size issues that are the subject of these ANPRMs; and revision of Daily Values based on the complete set of Dietary Reference Intake reports by the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences.

The prospect of numerous, incremental changes to the nutrition label simply is not in the best interest of consumers and is unacceptable to the food industry. Frequent nutrition label changes are likely to confuse consumers and impose substantial costs on the food industry. Therefore, FPA urges FDA to fully coordinate rulemakings to achieve a single set of required changes to nutrition labels within a single time frame.

Notification to Anticipate Additional FPA Comments

FPA had requested that the Agency allow additional time to sufficiently explore background data necessary to respond to the questions in the above ANPRMs. The Agency relied closely on

2001-2002 NHANES data and other food consumption data in preparing the ANPRMs. However, any summary information about the most current food consumption patterns of Americans is not yet available to the public or other stakeholders. This information is critical to make an informed response to the ANPRM questions about calories and serving size, but the 2001-2002 NHANES summary tables on food consumption patterns and nutrient intakes have just been released for formal review and clearance.¹⁴

Additionally, since consumers widely recognize and use the Nutrition Facts panel on food and beverage products to make purchase decisions, it is imperative that consumer understanding of, use of, and performance with food label information achieve desired goals. While some preliminary information from FDA consumer research about consumer use of nutrition labeling was included in its *Calories Count* report (Appendix G), final reports of such research have not been made publicly available.¹⁵ Final reports of these FDA consumer research projects also are important in making informed response to the ANPRM questions about calories and serving size.

Further, because of the important synergy between the 2005 Dietary Guidelines, MyPyramid, and the Nutrition Facts panel, the consumer research studies that supported development of the Guidelines and MyPyramid are essential to understand contemporary consumer beliefs about food, diet, and health. To date, only a summary of consumer research about the 2005 Dietary Guidelines has been made publicly available.¹⁶

Therefore, for the critical information needs of public and food industry stakeholders to completely respond to FDA's questions, FPA anticipates that it will provide additional comments to these dockets when NHANES summary tables for 2001-2003, final reports of FDA consumer research cited in its *Calories Count* report, and consumer research reports for the 2005 Dietary Guidelines and MyPyramid are available.

Summary

In sum, FPA recommends that FDA proceed with only voluntary changes to food and nutrition labeling about calories and serving size. Primary reasons to proceed with voluntary approaches include:

- FDA must conduct systematic research and evaluation to demonstrate that consumer use, comprehension of, and performance with food label information motivate behavior change before issuing any proposals for new food labeling requirements related to calories and serving size.

¹⁴ Personal communication with Alanna J. Mosfegh, Research Leader, Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, USDA; May 25, 2005.

¹⁵ *Calories Count*, report of the FDA Working Group on Obesity, March 12, 2004. Appendix G. Accessed at <http://www.cfsan.fda.gov/~dms/owg-toc.html> and <http://www.cfsan.fda.gov/~dms/owg-appg.html>.

¹⁶ *Consumer Communications Research Findings & Application, Dietary Guidelines for Americans*, DHHS and USDA. Accessed at <http://www.health.gov/dietaryguidelines/dga2005/toolkit/communications.htm>.

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- Government must recommit to public education about dietary guidance, food guidance, and use of label information and this must accompany any voluntary or required changes to food labeling.
- Current, contemporary American food consumption data are not yet available to evaluate and respond to questions about calories, serving size, or how to revise Reference Amounts Customarily Consumed (RACC) per eating occasion.
- Excessive focus on calories in labeling may undermine the “get the most nutrition from your calories” message of dietary and food guidance, and lead consumers to ignore foods or beverages with important nutrients, an unintended consequence that must be avoided.
- Calorie needs vary greatly and the individualized approach of MyPyramid may better serve the consumer.
- Current FDA regulations provide sufficient options to allow for voluntary dual labeling of calories or nutrition information in containers outside of single-serving container rules.
- FDA should consider new or alternative approaches beyond core questions about revision to RACCs.
- FDA must collect additional data to determine whether consumers can evaluate comparative claims about servings or portions.
- The prospect of numerous, incremental changes to the nutrition label is not in the consumer’s best interest and is unacceptable to the food industry. Any required labeling regulations need to be conducted simultaneously with one uniform implementation date.
- As additional consumer research and food consumption data are made available, FPA will submit additional comments to these ANPRMs.

Thank you for the opportunity to comment on these important issues.

Sincerely,



Robert Earl, MPH, RD
Senior Director, Nutrition Policy



Regina Hildwine
Senior Director, Food Labeling & Standards